

# ISO 9001:2000

## Impact on Harmonized Quality System Requirements in the Medical Device Industry



### An FDA Interactive Satellite Teleconference

Wednesday, April 25, 2001

Test: 12:30 - 1:00 p.m. EST

Program: 1:00 - 3:00 p.m. EST

Satellite Coordinates: C-Band Galaxy-3R, Trans 4 Vertical,  
Channel 4, Downlink Freq. 3780 MHz, Audio 6.2/6.8  
[http://www.fda.gov/cdrh/ohip/dcm/html/iso\\_9000.html](http://www.fda.gov/cdrh/ohip/dcm/html/iso_9000.html)

#### Why This Program is Important to Watch

On December 15, 2000, the International Organization for Standards (ISO) published revisions to its ISO 9000 series of quality management standards, some of which are directly relevant to medical devices. In this teleconference, moderator Mark Barnett and key speaker Kim Trautman will engage panels of experts from the medical device industry to explore how these revisions will affect the industry.

Topics of discussion will include how will the revised standards affect the recently harmonized quality system requirements for medical devices now in effect between Australia, Canada, the European Union, Japan, and the U.S.? And now that the requirements in the ISO 9001 base standard have changed drastically, how will this affect ISO 13485 and 13488, which have direct applicability to medical devices?

Viewers will have the opportunity to question the panelists live via telephone, fax, and e-mail.

#### Panelists

- Moderated by Mark Barnett, MPH, Communications Director, CDRH
- Kimberly Trautman, Office of Compliance, CDRH
- Industry Consultants
- And representatives from Health Canada and Lucent Technologies

You may e-mail questions to the panelists prior to the teleconference at:  
[tvquestion@cdrh.fda.gov](mailto:tvquestion@cdrh.fda.gov).

#### What You Need to Watch the Teleconference

To watch this teleconference, you will need a steerable analog satellite dish capable of receiving a C-Band transmission. This is a free program - it will not be scrambled.

#### Watching the Live Broadcast

1. This program will be carried live on the GE TiP-TV Satellite Network. Many radiology departments have GE-TiP TV. To find out if your facility is a subscriber, call toll free at 1-877-438-4788.

2. Some health care facilities have their own satellite dishes. If your facility has a satellite dish, ask your teleconference coordinator to make this program available (to "downlink").

3. There are many downlink sites that charge a moderate fee. Here are some places to go for information and help: Universities, libraries, vocational schools, community colleges, public schools, video rental, sales or production businesses, and cable companies (ask if they can downlink the program for you and send it to your meeting site via the local cable).

4. If the above services are unavailable, please e-mail [dcmo@cdrh.fda.gov](mailto:dcmo@cdrh.fda.gov) for help in locating a site to view this program.

For additional information about FDA's CDRH Division of Communications programming and programs, see:  
[http://www.fda.gov/cdrh/ohip/dcm/html/iso\\_9000.html](http://www.fda.gov/cdrh/ohip/dcm/html/iso_9000.html)